Consolidated Framework for Implementation Research (CFIR) to identify facilitators and barriers regarding the following: inner setting, outer setting, individuals involved, and intervention (SBIRT). The six-phase framework of Thematic Analysis (TA) was employed to analyze the data. We specifically used the deductive method to analyze the data with a pre-determined theory in mind (CFIR) to move to hypothesis building, and coding the data. RESULTS/ANTICIPATED RESULTS: Contrary to research conducted outside of the schools under the auspices that schools do not have the time or interest in providing school-based substance use interventions, several themes emerged identifying a receptivity, willingness, and eagerness to provide these services. Specifically, school-based mental health professionals (i.e., school counselors, school psychologists) being aware of adolescent substance use in their schools, but not knowing how to appropriately handle such disclosures. Further, school-based mental health personnel indicated that they would want additional training on how to identify and provide services to adolescents with substance use needs. School-based administrators also indicated a receptivity to addressing substance use with an acknowledgement that schools would need to move from a punitive model for substance use infractions to a treatment model. Some identified barriers to implementation included lack of awareness of community treatment settings for referrals and anonymity or lack thereof of substance use screening. DISCUSSION/SIGNIFICANCE OF IMPACT: While the data analyzed come from a limited sample in one school district, the present study found that schools could be potential settings for the early identification and intervention of adolescent substance use. Findings from this study contribute to our understanding of school and community receptivity to school-based interventions. Future research should identify training needs of school-based mental health personnel to assist in the early identification and prevention of substance use disorders.

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An Analysis of Current Trends in Inclusion of Historically Underrepresented Populations in Clinical Trials: Women and Geriatrics

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OBJECTIVES/SPECIFIC AIMS: Clinical trials (CTs) play an important role in developing new treatments, expanding or refining treatments that are already available, and/or identifying behavioral changes that can prolong or improve the lives of subjects. CTs are also conducted to understand normal human physiology, pathophysiology, and factors associated with health outcomes. Results from CTs are then used to determine the safety and efficacy of medications or treatment. CT participants should reflect the diversity of those receiving the treatments because, exclusion of specific populations in CTs may potentially result in knowledge gaps for clinicians and regulators. Historically, women and geriatrics have been underrepresented as CT participants. For women, this is the result of Food and Drug Administration (FDA) action in 1977 which restricted women with childbearing potential from participating in phase I and early phase II CTs after thousands of birth defects resulted from thalidomide usage during pregnancy. While the U.S. Government Accountability Office's 1992 and 2001 reports documented an increased female inclusion in later stages of CTs, earlier phases of CTs were still lacking. Likewise, older adults and geriatrics have been excluded in CTs arbitrarily or to avoid adverse events associated with drug-drug interactions and comorbidities. Over the past few decades, the FDA has worked to address this issue and increase diversity and transparency in CTs. In 2015, the FDA's Action Plan for Food and Drug Administration Safety and Innovation Act (FDASIA) Section 907 called for improved CT inclusion and reporting of demographic subgroups (sex, age, race, and ethnicity), highlighting three priority areas: quality, participation, and transparency. This research examines the current state of female inclusion in phase I and II CTs (2016 to 2017) and geriatric inclusion in phase III CTs (2010 to 2017). METHODS/STUDY POPULATION: To assess female representation in phase I and II CTs, data from 2016 CTs was extracted from clinicaltrials.gov. The average percentage of male and female participation in trials recruiting for males and females was determined; CTs conducted in only males or females (due to sex specific disease states) were excluded. The data was further differentiated into investigator-initiated and industry-sponsored trials to determine any differences in sex representation. Data from 2017 CTs on clinicaltrials.gov will be extracted and analyzed as well as 2016 to 2017 data from FDA novel drug approvals. To assess geriatric representation in phase III CTs, geriatric subsections of drug labels from novel drug applications approved between 2010 to 2017 were assessed for geriatric-specific information based on four areas: 1) reporting of CT including geriatrics, 2) reporting of percentage of CT participants ages 75+, 3) providing geriatric dosage recommendations, 4) determining product safety and efficacy for geriatrics. RESULTS/ANTICIPATED RESULTS: It is mandatory that all US CTs are registered on clinicaltrials.gov with the exception of Phase I studies, and results posted within 1 year of CT completion. In 2016, 916 phase I and 713 phase II CTs were registered on clinicaltrials.gov. Of these registered CTs, 4% of phase I and 9% of phase II CTs posted results. Of these, phase I studies included more males than females. Of these, phase I studies showed higher percentage of males (58%) than females (42%). In phase I/II, phase II, and phase II/III CTs, females were represented at a higher levels than males by 8-20% (Table 1). Phase I industry-sponsored and investigator-initiated trials and phase II/III investigator-initiated trials included less females than males (Table 2); all other types of CTs had more female than male subjects (Table 2). Preliminary findings will be expanded to include 2017 CTs and a wider pool of clinical trials will include all those associated with FDA novel drugs approved in 2016 and 2017. Of the 250 labels of novel drugs approved from 2010 to 2017 assessed for geriatric inclusion, 74% reported a CT including geriatrics, and 55% reported including CT participants ages 75+. Further, 31% provided geriatric dosage recommendations and 62% indicated insufficient evidence to determine product safety/efficacy for geriatrics (Figure 1). There was no consistent increase following the 2015 implementation of FDASIA section 907 in any of the four areas examined (Figure 2). Labels providing geriatric dosage recommendations were consistently the least fulfilled area across all years analyzed (Figure 3). DISCUSSION/SIGNIFICANCE OF IMPACT: A lack of inclusion of specific populations in CTs can lead to serious complications. For example, in 2013, the FDA required a lower recommended dose for women for drugs containing the sedative-hypnotic zolpidem (i.e. Ambien) due to persisting next morning drowsiness; the FDA arbitrarily recommended the dosage be halved from 10 mg to 5 mg as it found that women appeared to eliminate zolpidem from their bodies more slowly than men. Additionally, $35.7 million is spent annually on hospitalization from adverse drug reactions in the elderly. And, although government acts and initiatives have called for greater inclusion of certain populations like females and geriatrics in CTs, there is no penalty for exclusion. Problems like these may be avoided if these specific populations

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are included in CTs so that drugs can be properly studied. It may be preliminary to make conclusions about female representation in phase I clinical trials because it is not mandatory to register all phase I trials on clinicaltrials.gov, but further investigation will be conducted into FDA summary reports. Preliminary findings indicate that efforts to include female subjects may be effective in the subset of studies that reported their results. As of 2017, 51.3% of the U.S. population over 18 years old is female (U.S. Census Bureau). Early clinical trials often help to establish safety and dosing for phase III trials. Thus, it is pertinent that the inclusion rate is reflective of the general population at all clinical trial stages, not just pivotal, phase III trials. It would be prudent to monitor this trend as more studies report their results. Given that the average US life expectancy is now 78 years and that elderly population is expected to double in coming decades (NIH, 2016), there is an urgent need to include this population in current and future clinical research. Geriatrics, particularly those age 75+, use more than a third of total prescription and over-the-counter medications sold in US (Merck Institute, 2014), but is severely underrepresented in CTs. The effects of polypharmacy and changes in drug metabolism with age increase the need for specific drug dosage recommendations for geriatrics. As there was no discernable difference in drug labels fulfilling areas examined before and after 2015, FDASIA implementation may not have impacted geriatric inclusion in CT for drugs approved between 2010 to 2017. As many of these CTs began prior to FDASIA 2012 signing and 2015 implementation, the legislation's full impact may occur in future years. Nonetheless, inadequate language currently found in geriatric drug labels can create challenges for clinicians when prescribing these medications for geriatric patients, potentially contributing to adverse drug events.

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Assessing Research Activity and Capacity of Community Based Organizations: Field Testing of the Community Research Activity Assessment Tool (CREAT)

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OBJECTIVES/SPECIFIC AIMS: 1. To assess the acceptability and feasibility and of an online self-assessment version of the Community REsearch Activity Assessment Tool (CREAT), an instrument to measure research capacity of CBOs. 2. To elicit CBO perspectives on their research and knowledge generation activities. METHODS/STUDY POPULATION: Thirteen CBOs who had previously partnered with an academic course on practice-based community health research were contacted and asked to participate in the field testing of the CREAT and provide feedback on areas of strength and areas for potential improvement. Eleven organizations completed the field testing, which began and ended with an in-person semi-structured interview with the online self-administration of the CREAT in the middle. The semi-structured interviews were audio-recorded with questions pertaining to topics such as: strengths and challenges of previous academic research partnerships, perceptions around the importance of research within the organization, thoughts and reactions to the CREAT, and general feedback about the CREAT. Results from the self-administered CREAT were used to test a scoring algorithm. Semi-structured interviews are being transcribed, pre-post responses to questions of strengths and challenges in engaging in research partnerships will be compared, and overall qualitative transcripts will be coded using grounded theory. RESULTS/ANTICIPATED RESULTS: Anticipated Results: The CREAT was acceptable and self-administration was feasible. Average time for completion of the online CREAT was 41 $\pm$ 13 min, and respondents did not need assistance from the interviewer to complete the online instrument. Suggestions for improvements focused on word choices and scale options. Respondents were aware of the importance of research activities for their CBOs, particularly for optimizing programmatic quality and services. Access to staff and financial resources were key barriers to strengthening research capacity, and respondents noted that engaging in research partnerships can also bring in additional resources. Interview transcription is still in progress along with the refinement of the codebook for the qualitative data collected. In alignment with objectives/goals outlined above, the results will be separated into the following four sections: CBO Research and Knowledge Generation Activities, Acceptability of the Tool, Feasibility of the Tool, and Refinement of the Tool. DISCUSSION/SIGNIFICANCE OF IMPACT: The online, self-administered CREAT instrument is acceptable and feasible for CBO respondents. Availability of a validated tool to assess research capacity of CBOs, developed and refined with input from community researchers, will support targeted research capacity building for CTSAs, community organizations and partners, thus strengthening collaborations. Translational scientists, public health systems and community health improvement depend on CBOs as partners in community-engaged research (CEnR). The CREAT will allow community members to more fully contribute their expertise to the development, implementation and evaluation of interventions, and to develop more equitable partnerships with researchers.

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Building Capacity for Community Engaged Research: Penn State University's Faculty Fellowship Program

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OBJECTIVES/SPECIFIC AIMS: To build capacity for community engaged, translational research in faculty across the university. METHODS/STUDY POPULATION: Each year, the Community Engagement Research Core (CERC) of the Penn State CTSI invites applications for one to two Community Engagement Faculty Fellowships. Applicant teams are comprised of a junior or mid-level investigator seeking to expand their work into the CEnR arena under the mentorship of a senior investigator with expertise in community engaged scholarship. The fellow must develop a plan for the mentoring year, including a timeline, activities to be undertaken together, knowledge to be acquired, deliverables, and a budget. The funding supports two course releases or the clinical equivalent for the fellow, and a small budget to support the mentor's research program. Proposals are evaluated using NIH scientific merit criteria. RESULTS/ANTICIPATED RESULTS: We are in our second year of the fellowship program. Two highly qualified fellows are currently working with established community-based mentors. The 2017-2018 fellowship team showcases how an effective mentor-fellow partnership can help move a fellow's work along the translational spectrum.

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